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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,107	OLSSON ET AL.	
	Examiner	Art Unit	
	Robert T. Crow	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *17 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on 12 April 2007 is acknowledged. The traversal is on the ground(s) that the mixture of claim 17 may be used within the context of the method recited by claims 1-16 of Group I. This is not found persuasive because the claims of the instant 371 national stage application were found to lack unity of invention (where unity of invention requires a special technical feature) due to the lack of a special technical feature between the different groups. Because Church et al disclose (PCT International Application Publication No. WO 00/53812, published 14 September 2000) mixtures of labeled and unlabeled nucleotides, wherein the labeled form is 1 mole percent of the mixture (page 36, lines 25-27), wherein the label is removed by chemical cleavage of a linker (page 6, lines 25-30), the technical feature linking the inventions of Groups I and II does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art. Thus, restriction under 35 USC 121 and 372 is proper.

Applicant further argues that claim 18 does not relate to mixtures of labeled and unlabeled nucleotides, and thus should be examined with Group I.

However, claim 18 is drawn to the kit of claim 17, further comprising an additional component. Because claim 17 is drawn to mixtures of labeled and unlabeled nucleotides, claim 18 is therefore also drawn to mixtures of labeled and unlabeled nucleotides, and the inclusion of claim 18 in Group II is therefore proper.

Applicant also argues because that the International Search Reports provides a search and examination of all of the claims, unity of invention should be maintained and the search does not present undue burden.

However, as indicated above, the technical feature linking the inventions of Groups I and II does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art. The claims of the instant 371 national stage application were found to lack unity of

invention (where unity of invention requires a special technical feature) due to the lack of a special technical feature between the different groups. Thus the burden of the search of these different inventions is moot, and restriction under 35 USC 121 and 372 is proper

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 17-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12 April 2007.

Claims 1-16 are under prosecution.

Preliminary Amendment

3. The Preliminary Amendments filed 4 October 2004 23 May 2005 are acknowledged. However, Applicant's amendments to the specification filed 23 May 2005 fail to comply with 37 CFR 1.121. Page 5 of the amendments to the specification filed 23 May 2005 seeks to replace the paragraph beginning with "Example 4" on page 30 of the specification with a paragraph reciting "Example 5." Page 6 of the amendments to the specification filed 23 May 2005 seeks to replace the paragraph beginning with "Example 5" on page 32 of the specification with a paragraph reciting "Example 6." Thus, the numbers of the examples have been changed without striking though the altered text and without underlining the new numbers.

4. It is emphasized that Applicant's response filed 30 November 2006 has been considered in the interest of customer service and compact prosecution. However, for the response to this Office Action to be complete, Applicant is **REQUIRED** to correct the errors listed above and file amendments that are compliant with 37 CFR 1.121. Failure to comply with this requirement will be considered **nonresponsive**.

Specification

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

6. Claims 1 and 5 are objected to because of the following informalities:

A. Claim 1 has a period after the recitation "or 1-20 mole%" in line 16 of the claim.

B. Claim 5 contains the phrase "the the" in line 2. this appears to be a typographical error.

C. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-16 are indefinite in claim 1, which recites the limitation "within the range of 1-50 mole%, 1-40 mole% 1-30 mole%, or 1-20 mole%" in lines 15-16 of claim 1. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961);

Ex parte Hall, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation 1-50 mole %, and the claim also recites 1-20 mole % which is the narrower statement of the range/limitation.

Claim 2 is indefinite in the recitation "within the range of 5-50 mole%, 5-40 mole% 5-30 mole%, or 5-20 mole%" in lines 3-4 of claim 2. As noted above, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

Claim 3 is indefinite in the recitation "within the range of 10-50 mole%, 10-40 mole% 10-30 mole%, or 10-20 mole%" in lines 3-4 of claim 3. As noted above, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

Claim 5 is indefinite in the recitation "the means for attachment" in line 2 of the claim. The recitation "the means for attachment" lacks antecedent basis because the previous claims to not recite a "means for attachment." It is suggested that the phrase "the means for attachment" be amended to "a means for attachment to the carrier."

Claims 10-12 are indefinite in claim 10, which recites the limitation "the fluorophore" in line 2 of claim 10. The recitation "the fluorophore" lacks antecedent basis because the previous claims to not recite a "fluorophore." It is suggested that the word "the" be amended to "a."

Claim 12 is indefinite in recitation "the exposed thiol group" in line 2 of the claim. The recitation "the exposed thiol group" lacks antecedent basis because neither claim 10 nor claim 1 recite an "exposed thiol group." It is suggested that the word "the" be amended to "an."

Regarding claims 12 and 16, the phrase "such as" in line 3 of claim 12 and in line 5 of claim 16 renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 13 is indefinite in the recitation "the linker" in line 2 of the claim. The recitation "the linker" lacks antecedent basis in the "cleavable link" of independent claim 1. It is suggested that the word "the" be amended to "a." Claim 13 is further indefinite in the recitation "the disulfide bridge" in lines 2-3 of the claim. The recitation "the disulfide bridge" lacks antecedent basis because the previous claims to not recite a "disulfide bridge." It is suggested that the word "the" be amended to "a."

Claim 14 is indefinite in the recitation "a pH below 7, preferably at a pH below 6.5, and mre preferably at a pH below 6" at the of claim 14. As noted above, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

Regarding claim 16, the phrase "various proteins...including" in lines 6-7 of claim 16 renders the claim indefinite because the words "various" and "including" does not clearly set for the metes and bound of the claims, and thus leads to confusion over the intended scope of the claim.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly

owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-10, 13, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawashima et al (PCT International Application No. WO 98/44152, published 8 October 1998) in view of Urdea et al (U.S. Patent No. 4,910,300, issued 20 March 1990).

Regarding claim 1, Kawashima et al teach a method for determining the sequence of a nucleic acid. In a single exemplary embodiment, Kawashima et al teach providing a single stranded form of a nucleic acid; i.e., a single stranded target nucleic acid (page 5, lines 15-20). The single stranded nucleic acid molecule is then hybridized to a primer to form a template/primer complex (page 5, lines 15-20). The primer is enzymatically extended by addition of a polymerase and extension with at least one nucleotide (page 6, lines 1-5) wherein the at least one nucleotide is a mixture comprising less than 50% of a labeled form of the at least one nucleotide (page 16, lines 15-23). The extension product comprising the labeled nucleotide is then detected (page 6, lines 6-10); because a given (i.e., single) nucleotide is provided in the extension step (page 6, lines 1-5), the type of nucleotide incorporated is known. Kawashima et al also teach the extension and detection steps are repeated at least once (page 6, lines 10-15).

While Kawashima et al teach the labels are fluorescent labels (page 7, lines 15-22), and that the labels are removed (page 6, lines 25-26), Kawashima et al do not explicitly teach a disulfide linker between the label and the nucleotide.

However, Urdea et al teach detectably labeled nucleotides (column 8, lines 20-60), wherein the detectable label is a fluorescent label (column 4, lines 5-10) and is linked to the nucleotide with a cleavable linker in the form of a disulfide linker (column 8, lines 20-60). Urdea et al further teach that the

nucleotides having the linkers and labels have the added advantage of being inexpensively synthesized in large quantity (column 2, lines 15-40).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the method comprising the use of labeled nucleotides as taught by Kawashima et al with the labeled nucleotides having a disulfide linker as taught by Urdea et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a method having the added advantage of having a decreased cost as a result of being inexpensively synthesized in large quantity as explicitly taught by Urdea et al (column 2, lines 15-40).

Regarding claims 2-3, method of claim 1 is discussed above. Kawashima et al also teach the amount of labeled derivative of the at least one nucleotide is within the range of 10-50 mole %; i.e., less than 50% (page 16, lines 15-23).

Regarding claim 4, method of claim 1 is discussed above. Kawashima et al also teach the single stranded nucleic acid is attached to a carrier; namely, immobilized to a surface of a bead (page 9, lines 20-25).

Regarding claim 5, method of claim 4 is discussed above. Kawashima et al also teach the means for attachment is specific binding to biotin/streptavidin (page 9, lines 10-15).

Regarding claim 6, method of claim 4 is discussed above. Kawashima et al also teach the carrier is a bead (page 9, lines 20-25).

Regarding claims 7-8, method of claim 1 is discussed above. Kawashima et al also teach the label is neutralized after the detection step by photobleaching; namely, laser bleaching of the fluorophores, which are labels (page 18, lines 13-19). Because labels are photobleached the after several extension and detection steps (page 18, lines 13-19), the removal occurs after at least one repetition of the detection step.

Regarding claim 9, method of claim 1 is discussed above. Kawashima et al also teach the link between the incorporated nucleotide and the label is cleaved; namely, labels are removed periodically

(page 6, lines 25-26). Because labels are periodically removed and the extension and detection steps are repeated at least once (page 6, lines 10-15), the removal occurs after at least one repetition of the detection step.

Regarding claim 10, method of claim 1 is discussed above. Kawashima et al do not teach a disulfide linker between the label and the nucleotide.

However, Urdea et al teach detectably labeled nucleotides (column 8, lines 20-60), wherein the detectable label is a fluorescent label (column 4, lines 5-10) and is linked to the nucleotide with a disulfide linker (column 8, lines 20-60). Urdea et al further teach that the nucleotides having the linkers and labels have the added advantage of being inexpensively synthesized in large quantity (column 2, lines 15-40).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the method comprising the use of labeled nucleotides as taught by Kawashima et al with the labeled nucleotides having a disulfide linker as taught by Urdea et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a method having the added advantage of having a decreased cost as a result of being inexpensively synthesized in large quantity as explicitly taught by Urdea et al (column 2, lines 15-40).

Regarding claim 13, the method of claim 1 is discussed above. While Kawashima et al teach the labels are fluorescent labels (page 7, lines 15-22), Kawashima et al do not teach a disulfide linker between the label and the base that is shorter than 8 atoms.

However, Urdea et al teach detectably labeled nucleotides (column 8, lines 20-60), wherein the detectable label is a fluorescent label (column 4, lines 5-10) and is linked to the nucleotide with a disulfide linker (column 8, lines 20-60). The linker between the disulfide bridge and the base is less than 8 atoms; namely, Formula 13 has label R1, a disulfide for R2, x is one CH2 linker, and NH connects to the base (column 8, lines 20-60). Urdea et al further teach that the nucleotides having the linkers of the claimed

length and the fluorescent labels have the added advantage of being inexpensively synthesized in large quantity (column 2, lines 15-40).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the method comprising the use of labeled nucleotides as taught by Kawashima et al with the labeled nucleotides having a disulfide linker of less than 8 atoms as taught by Urdea et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a method having the added advantage of having a decreased cost as a result of being inexpensively synthesized in large quantity as explicitly taught by Urdea et al (column 2, lines 15-40).

Regarding claim 16 method of claim 1 is discussed above. Kawashima et al also teach the agent Tween 20 is added (page 41, lines 5-11).

12. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawashima et al (PCT International Application No. WO 98/44152, published 8 October 1998) in view of Urdea et al (U.S. Patent No. 4,910,300, issued 20 March 1990) as applied to claim 10 above, and further in view of Verdine (U.S. Patent No. 5,783,384, issued 21 July 1998).

Regarding claim 11, the method of claim 10 is discussed above on pages 6-8. Kawashima et al do not teach cleavage is performed by addition of a reducing agent to expose a thiol.

However, Verdine teaches the attachment of molecules (i.e., peptides) to nucleotides using disulfide links, wherein the disulfide is cleaved by the addition of a reducing agent in the form of a thiol, which has the added advantage of allowing the determination of binding affinity of test molecules to the sequence (column 7, line 59-column 8, line 10).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the method comprising the use of disulfide linked labeled nucleotides as taught by Kawashima et al in view of Urdea et al with the reductive cleavage of the link to

generate a thiol as taught by Verdine with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a method having the added advantage of allowing the determination of binding affinity of test molecules to the sequence as explicitly taught by Verdine (column 7, line 59-column 8, line 10).

Regarding claim 12, the method of claim 10 is discussed above on pages 6-8. Kawashima et al do not teach the exposed thiol is capped with iodoacetamide.

However, Verdine et al teach the capping (i.e., alkylation) of exposed thiols with iodoacetamide, which has the added advantage of allowing monitoring of the production of the thiols (column 10, lines 25-32), thereby verifying that the reduction of the disulfide to a thiol has worked.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the method comprising the use of disulfide linked labeled nucleotides as taught by Kawashima et al in view of Urdea et al with the capping with iodoacetamide as taught by Verdine with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a method having the added advantage of allowing verification of the reductive production of free thiols by allowing monitoring of the production of the thiols as explicitly taught by Verdine (column 10, lines 25-32).

13. Claims 1 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawashima et al (PCT International Application No. WO 98/44152, published 8 October 1998) in view of Urdea et al (U.S. Patent No. 4,910,300, issued 20 March 1990) as applied to claim 1 above, and further in view of Uemori et al (PCT International Application Publication No. WO 97/24444, published 10 July 1997). Citations from Uemori et al are from the National Stage (U.S. Patent No. 6,395,526 B1, issued 28 May 2002). The National Stage is deemed an English language translation of the PCT.

Regarding claim 14, the method of claim 1 is discussed above on pages 6-7.

Neither Kawashima et al nor Urdea et al teach the extension with polymerase occurs at a pH below 7.

However, Uemori et al teach extension reactions of primer template/complexes using a DNA polymerase (Abstract) wherein the polymerase exhibits maximum activity at a pH of 6.5 (column 12, lines 13-16). Uemori et al also teach the DNA polymerase having the activity at pH 6.5 has the added advantage of higher primer extensibility (Abstract) with a lower error rate in DNA synthesis (column 13, lines 30-35), which improves the assay accuracy.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the method comprising the use of a DNA polymerase as taught by Kawashima et al in view of Urdea et al with the DNA polymerase of Uemori et al with a reasonable expectation of success. Use of the polymerase of Uemori et al would result in extension reactions performed at a pH 6.5. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a method wherein the polymerase reactions are performed at a pH of 6.5 for maximum activity of a polymerase that has the added advantage of higher primer extensibility with improved assay accuracy as a result of the lower error rate in DNA synthesis of the polymerase as explicitly taught by Uemori et al (Abstract and column 13, lines 30-35).

14. Claims 1 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawashima et al (PCT International Application No. WO 98/44152, published 8 October 1998) in view of Urdea et al (U.S. Patent No. 4,910,300, issued 20 March 1990) as applied to claim 1 above, and further in view of Lee et al (Nucleic Acids Res., vol. 20, pages 2471-2483 (1992))

Regarding claim 15, the method of claim 1 is discussed above on pages 6-7. Neither Kawashima et al nor Urdea et al teach dideoxynucleotides.

However, Lee et al teach a method of primer extension (i.e., incorporation) using fluorescently labeled dideoxynucleotides (Abstract), wherein the use dideoxy nucleotides in sequencing (i.e., determining the type of nucleotide added to a primer) has the added advantage of being the most durable and efficient method of DNA sequence and is the method of choice in large scale sequencing programs (Introduction).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the method of by Kawashima et al in view of Urdea et al with the dideoxynucleotides of Lee et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a method having the added advantage of being the most durable and efficient method of DNA sequence and is the method of choice in large scale sequencing programs as explicitly taught by Lee et al (Introduction).

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1 and 7-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 33-34 of copending Application No. 10/529,352 in view of Kawashima et al (PCT International Application No. WO 98/44152, published 8 October 1998). Both sets of claims are drawn to single stranded nucleic acid molecules, template/primer complexes, extension with a polymerase, proportions of labeled nucleotides with a cleavable link, and determining the type of nucleotide added to the primer.

The ribonucleic acid molecules of the '352 Application are a species of the instantly claimed nucleic acids. The '352 claims do not repeat extension and determination of the type of nucleotide.

However, Kawashima et al teach enzymatic extension of primer/template complexes by addition of a polymerase and extension with at least one nucleotide (page 6, lines 1-5), wherein the steps are repeated; namely, re-sequencing, which encompasses repetition of all of the steps, is performed, which has the added advantage of allowing analysis of large populations for polymorphisms (page 23, lines 8-19); polymorphisms are indicative of genetic disease.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified claims of the '352 Application with the repetition of steps as taught by Kawashima et al to obtain the instantly claimed method with a reasonable expectation of success.. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a method having the added advantage of allowing analysis of large populations for genetic diseases by screening for polymorphisms as explicitly taught by Kawashima et al (page 23, lines 8-19).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571) 272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert T. Crow
Examiner
Art Unit 1634

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER